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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,946	04/15/2004	James R. Braig	OPTIS.086A	7280

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EXAMINER	
MUI, CHRISTINE T	
ART UNIT	**PAPER NUMBER**
1797	

NOTIFICATION DATE	DELIVERY MODE
10/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/824,946	BRAIG ET AL.	
	Examiner	Art Unit	
	Christine T. Mui	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *1-14, 33-44 and 53-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-32 and 45-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *16 September 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims1-14, drawn to product, classified in class 435, subclass 287.1.

   II. Claim 33-44 and 53-58, drawn to process, classified in class 422, subclass 82.05.

   III. Claims 15-32 and 45-52, drawn to product, classified in class 436, subclass 58.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product as claimed can be practiced with another materially different product.

3. The process of measuring the glucose concentration in human blood can be conducted by another materially different product than the one disclosed in the instant application. The glucose that is measured can be conducted by an a microfluidic device or a test strip that is subjected to a source of radiation or a blood glucose meter is

exposed to radiation and measurements are observed by a microprocessor that calculates the standard error within a confidence interval using normal statistical analysis.

4. Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require determining the concentration of the analyte . The subcombination has separate utility such as using electromagnetic radiation to measure the jointing of rock during underground mining or in supersonic and hypersonic target-tracking missiles.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

5. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product.

6. The system can be use electromagnetic radiation to measure the jointing of rock during underground mining or in supersonic and hypersonic target-tracking missiles or use infrared radiation to treat oncological disorders or to defoam aqueous systems.

7.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior

art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. During a telephone conversation with David Jankowski on 25 September 2007 a provisional election was made without traverse to prosecute the invention of Group IV, claims 15-32 and 45-52. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-44 and 53-58 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 26-32 and 45-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,296,706 to Braig et al (herein referred "Braig").

14. Regarding claims 26 and 45, the reference Braig discloses an anesthetic agent (sample) analyzer having six or more independent analytical channels (see abstract). In a preferred embodiment the air way adapter is formed of a disposable plastic and includes a plastic window in an optical path between the infrared detector and the infrared radiation source. Braig does not disclose moving the window more than one micron and still be able to detect the sample's concentration. As seen in Figure 5, there is an optical path of the detector 400 where infrared energy is emitted from a wideband infrared radiation source 500 (electromagnetic and infrared source). The infrared energy 502 that is emitted from the source 500 passes through an optical window 503 and through a first optical window 504 of an airway adapter 505. The infrared energy 502 passes through the gas being analyzed and is modulated as it passes through the airway adapter 505. The modulated infrared energy 502 then passes through a second optical window 506. The outputs from the detectors 534-544 and 546-556 are input into a processor 558 for determining the concentrations of the respective anesthetic agent gases from signals provided by the respective detectors using mathematical techniques (see column 9, line 66 – column 10, line 1-10; column 11, line 21-24 and column 12, line 11-12; Figure 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to still observe the concentration of a gas when the window moves a small amount such as a micron so a straight path between the detector and source can be created so that the most accurate concentration of the sample can be calculated.

15. Regarding claims 27-30 and 46-48, the reference Braig discloses an anesthetic agent gas analyzer where the output of radiation detectors are input into a processor for determining the concentrations of the respective anesthetic agent gases from signal provided by respective detectors using mathematical techniques. Braig does not disclose deviating the window a specific distance in microns while still observing the concentration of the gas sample. The output signals to the process 558 are substantially independent of the influence of ambient temperature changes because of the parallel-opposed configurations of the detectors. By disposing the anesthetic agent detectors and the reference detectors each sample is exposed to the incident infrared radiation while the other is shielded from the incident infrared radiation (see column 11, lines 21-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the optical path or the planarity deviate between 2 and 10 microns and have the microprocessor still calculate the concentration of the sample with accuracy to display the durability and accuracy of the microprocessor and the apparatus because in order to detect the concentrations, there needs to be a parallel opposed configuration, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

16. Regarding claims 31 and 51, the claim is directed toward the intended use of the analyzer measure safe levels of anesthesia in a patient in accordance with regulatory authorities and/or medical practitioners. Braig does not disclose the concentration that is calculated meets requirements imposed by a regulatory authority and/or medical

practitioner. The reference Braig discloses the analyzer for anesthetic agent gases such as carbon dioxide, nitrous oxide and other anesthetic ages contained in respiratory gases of an anesthetized patient. The analyzer relates to a multichannel mainstream anesthetic agent which measures the partial pressures of constituent gases in a respiratory gas stream (see column 1, lines 10-15). It is interpreted by the examiner that the levels of anesthetic agent gases that are measured can be measured and compared to regulatory authority and/or medical practitioners safety requirement level if samples are taken from a patient under anesthesia. It would have been obvious to one having ordinary skill in the art at the time the invention was made to measure anesthetic level in a patient's respiratory tract to ensure safe levels of a gas if they are undergoing a procedure such as surgery where a safe and appropriate amount of anesthesia is given to the patient so that one does not overdose.

17. Regarding claims 32 and 52, the claimed is directed toward the intended use of the readings to determine acceptable diagnostic results from the readings of the detectors. The reference Braig discloses the output reading from the detectors are input into a processor for determining the concentration of the respective anesthetic agent gases from the signals provided by the detectors (see column 11, lines 21-27). It is interpreted by the examiner that the readings that are input in the processor 558 from signals of the detectors and converted into concentration of the anesthetic gases are ones that are within an acceptable range for the result or can be fixed by programming the processor to determine acceptable error ranges. It would have been obvious to use the concentrations that are detected from the detector and calculated by the processor,

the concentrations will report values that are of sufficient accuracy for results so that one can observe the effect of a gas concentration within a patient.

18. Claims 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braig, and further in view of USP 6,463,391 to Early (herein referred "Early").

19. Regarding claims 15 and 21, the reference Braig discloses the claimed invention except for where the system computes the estimated concentration of the detected analyte with a standard error or RMS and a confidence interval. Early discloses an apparatus and method for calculating error analysis of at least one confidence interval of an unknown sample value (see column 3, lines 23-25, 34-36). In one calculation, data is recorded on a worksheet for one unknown sample a which included the following parameters; sample column, concentration column, error column, 90% prediction interval (90%PI), 95% prediction interval (95%PI), 99% prediction interval (99%PI) (see column 7, lines 53-67; Figure 8). The confidence interval is calculated using classical statistical analysis using t test and prediction intervals such as 95% (column 8, lines 5-14, 51-53), therefore it would have been obvious to also calculate the RMS of a sample using the same classical statistical analysis. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have a system that calculates the concentration from a processor that calculates the concentration along with the standard error, root means squared and confidence interval of a samples so that one can determine how closely the samples are in concentration or how diverse they are.

20. Regarding claims 16-20 and 22-25, the reference Braig discloses the claimed invention except for calculating the standard error or RMS of a sample that is being tested under a certain concentration. Early discloses a method for calculating the standard error of an unknown sample where the standard error is calculated for unknown samples (see column 7, lines 55-59). The confidence interval is also calculated using t test using classical statistical analysis (column 8, lines 5-14, 51-53), therefore it would have been obvious to also calculate the RMS of a sample using the same classical statistical analysis It would have been obvious to one having ordinary skill in the art at the time the invention was made to calculate a standard error or RMS of the sample set with low concentration using classical statistical analysis so that one can determine the most accurate and precise concentration, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine T. Mui whose telephone number is (571) 270-3243. The examiner can normally be reached on Monday-Friday 8-5; Alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

WALTER D. GRIFFIN
SUPERVISORY PATENT EXAMINER